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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,432	07/17/2003	Gary A. Strobel	34373/0007	4064

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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,432	STROBEL ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72 and 77-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72 and 77-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of "*aureus*" in claim 86.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/4/06 has been entered.

Claims 72 and 77-89 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72 and 77-89 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No clear basis or support is found in the present specification for the recitation of "between zero and 2800 ppm" or "between zero and 2500 ppm" as now recited. If applicant is attempting to exclude zero, the recitation would also exclude 2800 ppm. The specification clearly is directed to "less than", and for purposes of examination the claims are interpreted to include zero and 2800 ppm.

No clear basis or support is found in the present specification for the various combinations of volatiles as now claimed. Applicant did not indicate the source for the amendments in the specification with any specificity.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72 and 77-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 72 and 77-89 are vague and indefinite in the recitation of "between zero and 2800 ppm" or "between zero and 2500 ppm" as now recited. This phrase can be interpreted as including zero and 2800 or excluding them. No definition is provided in the as-filed specification. See also the new matter rejection *supra.*

In addition, it is unclear what is intended by "in a closed environment", since the size of the environment is not clearly defined. A closed environment includes a Petri dish or a test tube but also a panel truck, a food storage facility, such as a warehouse, or an apartment building. The further ingredients of the composition are not defined. Moreover, it is unclear what is intended to be encompassed by bacteria that "contaminate buildings". The specification is directed to volatiles that "kill bacteria that contaminate food such as *S. aureus* and *E. coli* (Table 11) and have been found to be lethal to *Stachybotrys* sp. (contaminator of homes and public buildings) and also a number of wood decay fungi.

The inhibition of growth as claim designated appears contradictory and confusing regarding an "effective amount" wherein the maximum is 2800 ppm or 2500 ppm of a volatile, or almost that amount. The nexus between "a bacterium (or fungus) that contaminates post harvest food or building" and the recited "closed environment" cannot be ascertained. Also, it is unclear whether the volatile organic compounds recited in minute amounts are, in fact, active ingredients in the effective amount of the composition.

Claims 80 and 81 improperly depend on claim 72 for the recitation of two or three components to be applied together while claim 72 recites them in the alternative.

Claims 83 and 87 improperly depend on claim 72 for the recitation of two microorganisms together while claim 72 recites them in the alternative.

Claim 89 is vague, indefinite and confusing in denoting *Stachybotrys* as a bacterium. It is a fungus.

Claims 80, 81, 83 and 87 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

With respect to "effective amount" applicant has not defined the purpose of the effective amount with any particularity. It is unclear how an amount effective to inhibit the growth of any bacterium or fungus can be determined if all by contacting any "closed environment" with a composition comprising the volatiles of interest in trace amounts that may be effective for some purpose. That applicant has specific delivery systems and tests for efficacy is noted. However, the tests are not within the context of the invention as claimed which covers application to any post harvest food or any building. There is no claim designated limitation to indicate "contact" of the bacterium or fungus in a closed environment clearly correlated to post harvest food or buildings.

Therefore the rejection is deemed proper and it is adhered to.

Claims 84-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of certain bacteria or fungi with a mixture of volatile compounds does not reasonably provide enablement for the inhibition of any bacteria or fungi that contaminate post harvest food or buildings using certain volatiles singly or in combination in any amount..

The inhibition of bacteria and fungi with volatile compounds is unpredictable particularly when using trace amounts in a composition. The specification as-filed does not provide sufficient guidelines or teachings for the inhibition of any and all bacteria or fungi that contaminate post harvest food or buildings or the scope of "closed" with respect to an environment. Post harvest food includes fruit, vegetables, fish, shellfish and dairy products. It is noted that some of the volatiles listed are toxic. The teachings provided in the as-filed

specification would not have enabled one skilled in the art to "use" the *Muscodor*-derived volatile compounds to inhibit any bacteria or fungi that contaminate post harvest food or buildings, in the claim designated methods. The guidance provided in the specification is not adequate to lead persons of skill in the art toward success in inhibiting all the organisms recited in the process encompassed by the claims in a predictable manner, because the effects of single compounds are not set forth with any particularity and the amounts required for effectiveness are not specified with sufficient particularity. It is apparent that applicant is offering an "invitation to experiment" to those skilled in the art to perform various techniques and to determine for themselves whether they have inhibited the growth of a microbe, insect or nematode. See Genentech, Inc. v Novo Nordisk A/S., 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, In re Scarbrough, 182 USPQ 298, 302 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying out investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves. In re Gardner et al., 166 USPQ 138 (1970)").

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to identify the volatile compound(s) necessary to inhibit the growth of any and all bacteria or fungi that contaminate post harvest food or buildings in the "closed" environments recited; limited amount of guidance and limited number of working examples in the specification directed to the treatment of a large variety of members of the organisms recited with combinations of compounds; the unpredictable nature of an invention directed to the use of single or specific combinations of volatile compounds in any amount to inhibit the growth of any and all any bacteria or fungi that contaminate post harvest food or buildings; the unpredictability in the art and breadth of the claims directed to the use of certain volatiles singly or in certain combinations to inhibit the growth of any and all any bacteria or fungi that contaminate post harvest food or buildings. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that closed containers of food have been treated and that those of ordinary skill in the art know how to use chemical fumigants in order to obtain inhibition of various bacteria and fungi in closed environments. However, in the instant case the nature of the composition to be used is not defined with sufficient particularity to treat any bacteria or fungi that contaminate post harvest food or buildings because there is no claim designated requirement, for example that the post harvest food or buildings be a "closed environment" with respect to volatile diffusion.

As to the variation of dosages, it is unclear how this is done for a composition wherein the active components are not clearly delineated and which comprises between zero and 2800 ppm isobutyric acid or between zero and 2500 ppm 2-methyl-1-butanol, which can be interpreted and as lacking in isobutyric acid or 2-methyl-1-butanol. Therefore, knowledge in the art of the use of chemical fumigants is not clearly relevant to the invention as claimed.

Applicant presents data to show experiments against specific fungi and one bacterium in specific Petri dish environments, all of which appear to be sealed and wherein post-harvest pathogens in plants using fumigation boxes wherein the microbes are treated with the volatile for extended period of time.. However the claims are directed to the inhibition of growth of in a closed environment of any bacteria or fungi that contaminate post harvest food or buildings. The data presented in the declaration are directed to the inhibition of growth of the few fungi and one bacterium, specifically *Penicillium expansum*, *Rhizoctonia solani, Aspergillus niger, Geotrichum citri-aurantii, Erwinia carotorova* and *Cladosporium cladosporioides.* While results are impressive, these findings cannot be properly extrapolated to any and all any bacteria or fungi that contaminate post harvest food or buildings. It is well known that at least some of the touted volatiles are produced by microbes, the growth of which is clearly not inhibited thereby, particularly in amounts that encompass the absence of volatiles. For example, Nout adequately demonstrate that a mixture of volatiles comprising 3-methyl-1-butanol and/or 2-methyl-1-butanol are ineffective to inhibit the growth of microbes such as *P. kluyveri, C. shehatae ,C. zeylanoides, C. guilliermondi* and *D. hanseii.* See, e.g., Tables 1-3. In addition.

Robinson *et al.* adequately demonstrate that exposure to a mixture of volatiles comprising isobutanol does not affect the growth of a fungus such as *Fusarium oxysporum.* See, e.g., Table 1. At least *P. kluyveri* and *Fusarium oxysporum* are post harvest pathogens.

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 77-82 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Sunesson *et al.* ((1995). Identification of volatile metabolites from five fungal species cultivated on two media. Applied and Environmental Microbiology, 61(8): 2911-2918.)

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit in a closed environment with certain compounds to inhibit their growth.

Sunesson *et al.* teach contacting fungi that contaminate buildings in a closed environment with 3-methyl-1-butanol and/or 2-methyl-1-butanol and/or 2-methyl-1-propanol (isobutyl alcohol). See, e.g., Table 1 (*P. commune).*

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Growth of the microbe is inhibited at least to some extent.

Claims 72, 78-81, and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Borjesson *et al*, (Applied and Environmental Microbiology. 56: 3705-3710, 1990)

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit in a closed environment with certain compounds to inhibit their growth.

Borjesson *et al.* teach contacting fungi that contaminate post harvest food such as cereals in a closed environment with 3-methyl-1-butanol and/or 2-methyl-1-propanol (isobutyl alcohol). See, e.g., Table 1.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Growth of the microbe is inhibited at least to some extent

Claims 72, 78-81, and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Borjesson *et al*, (Applied and Environmental Microbiology. 58: 2599-2605, 1992)

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit in a closed environment with certain compounds to inhibit their growth.

Borjesson *et al.* teach contacting fungi that contaminate post harvest food such as cereals in a closed environment with 2-methyl-1-butanol and/or 2-methyl-1-propanol (isobutyl alcohol). See, e.g., Table 1.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Growth of the microbe is inhibited at least to some extent

Claims 72, 77-83 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiviranta *et al.* (Central European Journal of Public Health (Cent. Eur. J. Public Health) 1998, Vol. 6, n°4, pp. 296-299).

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit in a closed environment with certain compounds to inhibit their growth.

Kiviranta *et al.* teach contacting bacteria that contaminate buildings and post harvest food in a closed environment with 3-methyl-1-butanol and/or 2-methyl-1-butanol and/or 2-methyl-1-propanol (isobutyl alcohol) and/or ethyl butanoate (ethyl butyrate). See, e.g., Table 1 (*Klebsiella pneumoniae).*

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance

with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Growth of the microbe is inhibited at least to some extent.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651